APR 0 1 2003

510(k) Summary of Safety and Effectiveness

K023794
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(1) **Submitter's name:** Encore Orthopedics, Inc.
Submitter's address: 9800 Metric Blvd, Austin, TX 78758
Submitter's telephone number: (512) 834-6255
Contact person: Debbie De Los Santos
Date summary prepared: November 12, 2002

(2) **Trade or proprietary device name:** FMP Constrained Liner
Common or usual name: Constrained Liner
Classification name: Class II (Special Controls)

(3) **Guidance Document:**
"Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis; Guidance for Industry and FDA"

(4) **Subject device description:**
The constrained liner is first snapped into the shell and a ridge or lip around the outside of the liner engages a groove on the inside of the shell to provide a positive lock. The femoral head is inserted into the constrained liner and the locking ring secures the head into the liner.

The Constrained Liner consists of an UHMWPE insert conforming to ASTM F648 and a titanium alloy locking ring conforming to ASTM F136 or ASTM F620. The ID of the liners is 28 mm and the minimum thickness of the insert is 6 mm. The constrained liner is to be used in conjunction with the acetabular shells previously cleared in K973199, K974093, and K974095.

5) **Subject device intended use:**
The FMP Constrained Liner is intended to replace a hip joint. The device is intended for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered.

(6) **Risk Analysis:**

Identified Risk	Mitigation Measures	Acceptance Criteria	Results of Mitigation	Acceptance Criteria Met?
Infection	• Implants sold as sterile devices	• Must provide a SAL of 10^{-6}	• See Sterility below.	YES
Adverse Tissue Reaction	• Establish material and performance characteristics	• Must meet the following standards: ASTM F136-98 ASTM F620-00 ASTM F648-00	• See Standards Conformity below.	YES
Pain and/or loss of function	• Establish material and performance characteristics	• Must meet the following standards: ASTM F136-98 ASTM F620-00 ASTM F648-00	• See Standards Conformity below.	YES
	• Include precautions and intended use on labeling and package inserts.	• Must include the precautions and intended use provided in the guidance document.	• See Labeling below and Intended Use above.	
Revision	• Establish material and performance characteristics	• Must meet the following standards: ASTM F136-98 ASTM F620-00	• See Standards Conformity below.	YES

Identified Risk	Mitigation Measures	Acceptance Criteria	Results of Mitigation	Acceptance Criteria Met?
		ASTM F648-00		
	• Include precautions and intended use on labeling and package inserts.	• Must include the precautions and intended use provided in the guidance document.	• See Labeling below and Intended Use above.	
Device disassembly	• Femoral head lever-out testing	• Must meet or exceed the lever-out forces for Encore bipolar acetabulum	• Testing was performed to show lever out mode exceeds those of the bipolar.	YES

Sterility

All components are supplied sterile in triple sealed containers maintaining double sterile barriers. A combination of pouches and/or trays is used to provide the operating room staff with easy handling of the components. One hundred per cent visual examination of the package seals is performed and recorded. Sterilization is accomplished using gamma radiation (minimum 25 kGy) and is verified by dose validation per ANSI/AAMI/ ISO11137 –94 and EN552 to achieve a sterility assurance level of 10^{-6}. In addition, *B. pumilus* biological indicators (population 10^{6}) are utilized as a secondary verification. No testing is performed to determine if these parts are pyrogen free. Resterilization of components using autoclave steam cycle is prohibited.

Standards Conformity

As required by the risk analysis, performance characteristics for all materials used in manufacturing the components of the FMP Constrained Liner meet one of the following material standards:

ASTM F136-98, "Standard specification for wrought Titanium-6 Aluminum-4 Vanadium ELI alloy for surgical implant applications"

ASTM F620-00, "Standards specification for Titanium-6 Aluminum-4 Vanadium ELI alloy forgings for surgical implants"

ASTM F648-00, "Standard specifications for ultra-high molecular weight polyethylene powder and fabricated form for surgical implants"

Labeling

As required by the risk analysis, the caution statement, intended use, and precautions recommended in the guidance document are provided in the labeling, package insert and surgical technique for the FMP Constrained Liner.

Predicate Device

The FMP Constrained liner is similar or identical in regards to material, design, sizing, and indications to Biomet's RingLoc (K950202), Poly-Dial – Johnson & Johnson (P960054) and Trilogy – Zimmer (K021826).

K023794

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 01 2003

Ms. Debbie De Los Santos
Supervisor, Regulatory/Clinical Services
Encore Medical Corporation
9800 Metric Boulevard
Austin, Texas 78758

Re: K023794
Trade Name: FMP Constrained Liner
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip joint metal/polymer constrained cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWZ
Dated: January 21, 2003
Received: January 22, 2003

Dear Ms. De Los Santos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K023794

510(k) Number (if known): K023794

Device Name: FMP Constrained Liner

Indications For Use:

FMP Constrained Liner

Indications For Use

The FMP Constrained Liner is intended to replace a hip joint. The device is intended for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use ____
(per 21 CFR 801.109)
(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023794

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